K133006

APR 17 2014

510k SUMMARY

Title: neoV Diode Laser Family

Submitter: G.N.S neoLaser Ltd.
Ha'Eshel St. 7, 38900, Caesarea ISRAEL, PO Box 3203

Contact: Gil Shapira, CEO
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Date Prepared: August 29, 2013

Device Trade Name: neoV Diode Laser Family

Common Name: Laser surgical instrument for use in general surgery and dermatology

Classification Name: Instrument, surgical, powered laser
GEX
21 CFR 878.4810

Predicate Devices: Quanta Diode Laser Family (K100558)
Sheaumann Laser PL-1064 (K120938)

Device Description: The neoV Diode Laser Family are medical grade, solid-state, infrared diode lasers. They include 5 models – neoV810, neoV980, neoV1064 (LSV1064-10 and LSV1064-20), and neoV1470, and are designed to deliver continuous or pulsed, infrared laser energy at wavelengths of 810nm, 980nm, 1064nm, and 1470nm respectively, at power levels ranging from 8Watts up to 20Watts. The lasers are controlled via a high-resolution color touch screen. The touch screen display includes a user interface allowing selection of continuous, repeat pulse, or single pulse modes of operation as well as repetition rates, aiming beam settings, password key protection, and standby/ready mode selection. The units have an emergency shut off button on the front of the unit.

The Laser System: The laser system consists of an optical block which contains the laser diode, mirrors, lens, and aiming beam diode, an air cooling system, and electronics which include the color touch screen control panel. The unit utilizes an external low voltage power supply, as well as an external wired foot switch for laser activation.

The Delivery System: The delivery system consists of fiber optics and a hand-piece. Safety goggles and a safety sign are also provided with the unit.

Intended Use:

The neoV810 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The neoV980 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The neoV1064 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The neoV1470 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

Comparison: The neoV Diode Laser Family share the same technical and performance characteristics of the Quanta System QUANTA Diode Laser Family, and the Sheaumann PL-1064 systemn. Below is a table summarizing the comparison of the devices:

Specification	neoV Diode Laser Family	QUANTA Diode Laser Family	Sheaumann Laser PL-1064
Ref 510(k)	K133006	K100558	K120938
Wavelength [nm]	810, 980, 1064, 1470	808, 980, 1064, 1470	1064
Max Power [W]	8 – 810nm 20 – 980nm 10 – 1064nm (LSV1064-10) 20 – 1064nm (LSV1064-20) 10 – 1470nm	30 – 808nm 30 – 980nm 30 – 1064nm 15 – 1470nm	10 – 1064nm
Laser media	Diode	Diode	Diode
Output mode	CW, Pulsed, Single Pulse	CW, Pulsed, Single Pulse	CW, Pulsed, Single Pulse
Spot Size	0.7mm, 1mm, 1.5mm	0.6mm, 0.8mm, 1.2mm, 1.8mm, 2.4mm	0.7mm, 1.5mm, 3mm, 5mm, 7mm
Pulse Duration	100 µsec – 30 sec adjustable	3 msec – 2.5 sec adjustable	200 µsec – 30 sec adjustable
Aiming Beam	Green 532nm (<5mW)	Red 650nm (<5mW)	Red 635-650nm (<1mW)
Power Source	100 – 240 V, 47-63 Hz	100-240V, 50-60Hz	100-240V, 47-63Hz
User Interface	Color touch screen	Color touch screen	LCD touch screen
Laser Beam Delivery	Fiber	Fiber	Fiber
Dimensions [cm] and Weight [Kg]	22(L) X22(W) X10(H) 3.5Kg	39(L) X33(W)X25(H) 8Kg	22 X 25 X 12 3Kg

Summary: From a design and clinical perspective, the predicates and candidate laser devices, have the same technological characteristics and share the same intended use. Accordingly, the safety and effectiveness of the neoV Diode Laser Family is based upon a determination of the substantial equivalence to the predicate devices.

Non clinical Performance Data: The neoV Diode Laser family has been tested for compliance to IEC 60601-2-22: 2007 (Third Edition), Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment, IEC 60601-1: 2005 (Third Edition) Medical electrical equipment Part 1: General requirements for basic safety and essential performance and tested for compliance with all functional requirements, IEC 60825-1:2007 Safety of Laser Products – Part 1: Equipment classification, requirements and user's guide, EN 60601-1-2: 2007, Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests.

Clinical Performance Data: None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

G.N.S neoLaser Ltd.
Mr. Gil Shapira
Chief Executive Officer
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7 Ha'Eshel Street
Caesarea, 38900
ISRAEL

Re: K133006
Trade/Device Name: neo Diode Laser Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 16, 2014
Received: March 25, 2014

Dear Mr. Shapira:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133006

Device Name
neoV Diode Laser Family

Indications for Use *(Describe)*
The neoV810 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.
The neoV980 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.
The neoV1064 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.
The neoV1470 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
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For BSA